



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR PUBLIC HEALTH**

Steven L. Beshear
Governor

275 East Main Street, HS2E-B
Frankfort, Kentucky 40621
502) 564-4478
(502) 696-4923 Fax
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary



Kentucky Public Health
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To: All Kentucky Immunization Program (KIP) Providers
From: Laura Harrod, MS ED *Laura Harrod*
Kentucky Vaccine Accountability Section Coordinator

Date: October 1, 2014

Subject: **REVISED** Restitution Policy

The Center for Disease Control and Prevention (CDC) has instituted new Restitution Policy requirements for vaccine replenishment. To be compliant with these requirements, the KIP updated the current Restitution Policy. The changes include, if the KIP deems that the provider must repay lost vaccines, the repayment must be made within 90 days.

Please contact your KVP Field Staff or the KIP office at 502-564-4478 with any questions.

cc: Kraig Humbaugh, MD, MPH
Robert Brawley, MD, MPH, FSHEA
Margaret Jones, RN, BSN, BSEd
Jennifer Paulk
Craig Cooper
Lucy Senters

Enclosure

**Kentucky Immunization Program
Restitution Policy
Effective December 1, 2014**



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Introduction: Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration. Accountability of vaccine inventory is an essential requirement of participation in the Kentucky Immunization Program (KIP). The KIP includes the federal Vaccines for Children (VFC) Program, federal vaccine purchased for outbreaks and special programs, and state purchased vaccines. Vaccines are costly and federal and state funds for vaccine purchases are limited. The Restitution Policy requires any KIP provider deemed negligent by the KIP in any loss of KIP supplied vaccines to replace the lost vaccine on a dose-for-dose basis. Proof of purchase must be submitted to the program within 90 days.

Definitions:

Expired vaccine: Any vaccine with an expiration date that has passed.

Spoiled vaccine: Any vaccine that is stored or transported outside of the limits of the approved cold chain procedures or any vaccine that has been pre-drawn and not used within acceptable time frames. Always consult with KIP before determining that vaccine is spoiled.

Lost vaccine: Any vaccine ordered but not delivered or not delivered in a timely manner by the commercial carrier or delivery service that result in lost and/or spoiled vaccine.

Vaccine that is determined to be expired, spoiled, lost, or otherwise unusable is considered "wasted vaccine."

Policy: As part of the enrollment process for KIP, providers agree to comply with KIP requirements for ordering, storage, handling, and accountability of vaccine. The Provider Agreement, states that providers agree to: "replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis."

Beginning December 1, 2014 the provider will assume responsibility to replace wasted vaccine on a dose for dose basis within 90 days. There is a wide range of potential vaccine storage and handling issues that may result in wasted vaccine. The KIP will review each incident of wasted vaccine to determine whether restitution will be required. If restitution is required the practice will not receive additional KIP vaccine until replenishment with replacement vaccine is demonstrated and the problem that caused the wastage has been corrected.

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Situations Requiring Restitution: The following situations are examples of negligence that would lead to non-viable vaccine which may require restitution. This list is not exhaustive.

- Failure to rotate vaccine stock in order to use vaccine with the shortest expiration date first
- Failure to notify KIP a minimum of 90 days prior to vaccine expiration date
- Repeated waste of vaccine due to drawing up or preparing vaccine prior to patient screening
- Vaccine left out of the refrigerator or freezer resulting in vaccine reaching unacceptable temperatures
- Freezing vaccine that must be refrigerated
- Refrigerating vaccine that must be frozen
- Excessive ordering of vaccine that results in the expiration of vaccine before it can be used
- Provider staff failing to review, appropriately interpret and/or document refrigerator and/or freezer temperatures twice daily
- Vaccine that is considered spoiled due to temperature monitoring problems/errors
- Unplugged refrigerator/freezer unit or electrical breaker switched off for extended periods of time
- Failure to contact KIP when refrigerator or freezer malfunction results in temperature fluctuations
- Refrigerator or freezer malfunctions or power outages in which provider staff fails to follow their Emergency Vaccine Management Plan and/or fails to contact KIP
- Planned power outages in which provider staff fails to implement precautions to maintain appropriate storage of vaccine
- Vaccine received but unaccounted for in stock
- Transportation of vaccine inappropriately: unnecessary transportation of vaccine, transportation without KIP consent, and/or failure to appropriately maintain cold chain during transportation
- Failure to use single antigen vaccines or allowing single antigen vaccines to expire in favor of using combination vaccines
- Failure to notify KIP when provider's office will be closed for non-emergency situations i.e., holidays, trainings, parties, etc. KIP must be notified 3 weeks in advance of planned closing to prevent delivery of vaccines during this time
- Substantial vaccine wastage resulting from repeated or unresolved incidents from the list below of "Situation That Do Not Require Restitution"

Situations That Do Not Require Restitution: The following situations are examples of situations in which loss of vaccine would **NOT** require restitution. In these situations the provider practice is deemed to not be at fault. This list is not exhaustive.

- Vaccine is damaged, improperly stored during transit, or not delivered in a timely manner by commercial carrier or delivery service.
- Provider staff moved vaccine to their back-up location as outlined in their Vaccine Management Plan, in anticipation of power storage or due to refrigerator or freezer malfunction and the back-up location experienced power outage or equipment malfunction.
- Power interruption or failure due to storms or other weather conditions.
- Unanticipated refrigerator or freezer failure that occurs overnight, during the weekend or during a period of time when the provider staff is not present.

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- Partially used multi-dose vials of vaccine.
- A vial of vaccine that is accidentally dropped or broken by provider staff.
- Occasional instances of wasted vaccine due to provider staff error or last minute patient refusal.
- Expired vaccine the provider staff notified KIP about and redistribution made to another provider.
- Extraordinary situations not listed above which are deemed by KIP to be beyond the provider's control

Procedure for Restitution: Each incident reported will be reviewed on a case-by-case basis by KIP to determine whether restitution will be required or if extenuating circumstances exist.

- Call KIP if you suspect vaccine has been exposed to a situation that would deem it wasted.
- Fill out the Return and Adjustment Form (R&A) and fax it to (502) 696-4923. Keep a copy for your records and make a copy to send with wasted vaccines that are returned to McKesson Specialty Distribution.
- After the R&A Form is received by KIP, a return shipping label will be sent directly from McKesson Specialty Distribution to you in approximately 2-3 weeks.
- Once the shipping label is received, return the vaccine to McKesson Specialty Distribution without ice or gel packs but with "*filler*" so the vials will not break.
- If restitution is required, the provider will be asked to submit an invoice to KIP within 90 days showing they have purchased vaccine to replace the wasted vaccine. Providers should contact their insurance carrier to determine if there is coverage for lost vaccine.
- Failure to replace vaccine will result in a delay of future KIP vaccine orders.

Please contact KIP if you experience staff changes that impact vaccine storage and handling duties in the practice. Vaccine security depends on proper education and training. If you have any questions concerning this policy, please call KIP staff at (502) 564-4478.